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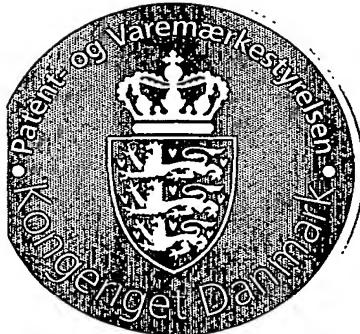
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Title: Stomiindretning

IPC: A 61 F 5/445; A 61 F 5/443

This is to certify that the attached documents are exact copies of the above mentioned patent application as originally filed.



PRIORITY DOCUMENT
SUBMITTED OR TRANSMITTED IN
COMPLIANCE WITH
RULE 17.1(a) OR (b)

Patent- og Varemærkestyrelsen
Økonomi- og Erhvervsministeriet

29 January 2004

Bo Zillo Tidemann

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10 JAN. 2003

Modtaget

TITLE**An Ostomy Appliance****BACKGROUND OF THE INVENTION****5 1. Field of the Invention**

The present invention relates to an ostomy appliance body side member, an ostomy appliance comprising such body side member, to an ostomy sealing member, and to a method of applying an ostomy appliance body side member around a stoma.

10

In connection with surgery for a number of diseases in the gastro-intestinal or urinary tract a consequence is, in many cases, that the colon, the ileum or the ureter has been exposed surgically and the patient is left with an abdominal stoma, or, in nephrostomy or ureterostomy, the ureter or a catheter is exposed in the back or the chest region or abdominal region, and the effluents or waste products of the body, which are conveyed through these organs, are discharged through the artificial orifice or opening and are collected in a collection bag, which is usually adhered to the skin by means of an adhesive wafer or plate having an inlet opening for accommodating the stoma/ureter/catheter. Also in connection with a fistula, the patient will have to rely on an appliance to collect the bodily material emerging from such opening.

Ostomy appliances are well known. Such appliances may be two-piece or one-piece appliances. In both types of appliances, an adhesive barrier member (or base plate) is attached to the wearer's abdomen/back/chest. In case of a one-piece appliance, a receiving member or bag is attached to the base plate. In case of a two-piece appliance, the adhesive barrier member forms part of a body side member and a receiving member or bag is attached releasably to the body side ostomy member for receiving exudates from the stoma.

30

When using one-piece appliances, the whole appliance, including the adhesive skin barrier securing the appliance to the skin is normally removed and replaced

by a fresh appliance. When using two-piece appliances, the body side ostomy member is left in place up to several days, and only the receiving member or bag attached to the body side member is replaced. The attachment means for attaching an ostomy receiving bag may e.g. be a system comprising matching

- 5 coupling rings or matching flanges and adhesive surfaces engaging with and sealing against a flange area of the body side member.

It is necessary to change the body side member of a two-piece appliance when the centre part of the adhesive wafer has been sufficiently deteriorated to allow

- 10 access of the aggressive exudates to the skin surrounding the stoma, irrespective of the fact that the wafer as such has a much longer wearing time. The access of aggressive exudates to the skin is causing skin problems.

Frequent changing of the body side member of a two-piece appliance is

- 15 undesirable due to the irritation of the skin and the quality of life of the user may be improved and the nuisance of the wearing of an ostomy appliance reduced if the intervals between exchanging of body side member can be increased.

The service time of the body side ostomy member depends *inter alia* of the

- 20 amount and the aggressiveness of the exudates and of the sealing between the stoma and the body side ostomy member.

The sealing depends on the fit to the stoma. Conventionally, only a limited number of standard appliances having holes of different size are available and

- 25 the user or an assistant must customise the body side member by cutting the edge of the hole to adapt the body side member to the stoma. However, the resulting hole may show an exposed edge which may injure the surface of the stoma e.g. when the user bends or turns due to the exposed edge of the carrier sheet which after cutting even may show a serrated edge.

2. Description of the Related Art

- Published International Patent Application No. WO 98/53771 discloses an ostomy appliance comprising a body side member comprising an adhesive wafer for securing the appliance to the user's skin, said wafer having a hole for receiving a stoma, and an optionally separately exchangeable receiving member or bag secured to the body side ostomy member for receiving secretions from the ostomy said ostomy appliance further comprising a sealing member disposed in the hole of the wafer surrounding the stoma wherein the sealing member disposed in the hole of the wafer surrounding the stoma, said sealing member having a hole for accommodating the stoma and said sealing member having balanced plastic and elastic properties allowing a better adaptation of the hole of the ostomy appliance to a stoma by a temporary enlarging the hole by everting or rolling up the inner rim of the hole for accommodating the stoma.
- When the ostomy appliance disclosed in WO 98/53771 has been placed over and around a stoma the adhesive sealing member may recover essentially to the original form to fit snugly to the stoma. The "release" may be performed using e.g. a finger or more or less automatically due to influence by elastic force, heat and/or humidity causing the sealing member to essentially resume its original shape.
- However, there is still a risk of constriction of the stoma due to elastic properties of the adhesive forming the wafer, which may cause harm to the stoma and which cannot be controlled after application.
- Thus, there is still a need for a sealing against a stoma ensuring that no leak occurs at the rim of the stoma in order to prolong the service time of the appliance, which ensures an easy adaptation to the actual user and at the same time reduces the risk of causing injury to or constriction of the stoma.

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SUMMARY OF THE INVENTION

- The invention relates to an ostomy appliance body side member comprising an adhesive wafer having a first adhesive surface for securing the appliance to the user's skin, said wafer having a second surface being covered with a carrier sheet which wafer has a hole for receiving a stoma wherein the part of the adhesive wafer surrounding the stoma shows balanced plastic and elastic properties allowing an adaptation of the size of the hole of the ostomy appliance to a stoma by enlarging the hole by rolling up the inner rim thereof for accommodating the stoma.
- 10 The invention furthermore relates to an ostomy sealing member in the form of a mouldable mass or ring which shows a sufficient adhesiveness to adhere to the skin and seal around an ostomy and between the ostomy and an ostomy appliance adapted to receive secretions from the stoma, which sealing member shows a sufficient cohesion to be removed in one piece, independently of removal of the ostomy appliance body side member without leaving remaining adhesive on the skin or the ostomy appliance, said sealing member having a hole for accommodating a stoma and said sealing member having balanced plastic and elastic properties allowing an enlarging of the hole for receiving a stoma by rolling the inner rim of the hole.

Still further, the invention relates to a method for applying an ostomy body side member comprising an adhesive wafer having a first surface for securing the appliance to the user's skin, said wafer having a second surface being covered with a carrier sheet which wafer has a hole for receiving a stoma wherein the part of the adhesive wafer surrounding the stoma shows balanced plastic and elastic properties allowing an adaptation of the size of the hole of the ostomy appliance to a stoma.

30 **Brief Description of the Drawings**

The invention is disclosed more in detail with reference to the drawings in which Fig. 1 shows a cross sectional view of a state of the art body side member,

Fig. 2 shows a cross sectional view of an embodiment of a body side member according to the invention,

Fig. 3 shows a cross sectional view of an embodiment of a sealing member according to the invention,

5 Fig. 4 shows a cross sectional view of the embodiment of Fig. 3 wherein the inner rim of a sealing member has been rolled up, and

Fig. 5 a view from the distal side of the separate sealing member of Fig. 3 in which the inner rim thereof has been partially rolled up to increase the size of the hole of an ostomy appliance of the invention and showing the indication of the 10 size of the hole placed on a release liner below, .

Detailed Description of the Present Invention

The present invention relates to an ostomy appliance body side member comprising an adhesive wafer having a first adhesive surface for securing the

15 appliance to the user's skin, said wafer having a second surface being covered with a carrier sheet which wafer has a hole for receiving a stoma wherein the part of the adhesive wafer surrounding the stoma shows balanced plastic and elastic properties allowing an adaptation of the size of the hole of the ostomy appliance to a stoma by enlarging the hole by rolling up the inner rim thereof for

20 accommodating the stoma and wherein the second surface of a part of the wafer surrounding the stoma shows adhesive properties compatible with the adhesive wafer.

The ostomy appliance of the invention provides an ostomy appliance enabling a 25 simple, safe and reliable customisation of the hole of a body side member without the use of tools and at the same time reduces the risk of causing injury to or constriction of the stoma.

When rolling up the inner rim of the hole, a torus is formed, and the torus will be 30 locked in its rolled position by the contact to an adhesive surface surrounding the stoma.

The present invention provides a freedom in the choice of the adhesive having the most suitable adhesive properties without having to consider the elasticity of the adhesive. Thus, a very elastic adhesive may be used, which is often desirable as such adhesives often show a high degree of cohesion rendering it more easy

- 5 to remove the adhesive without leaving residues on the skin and also often show a higher resistance to leaching of constituents of the adhesive prolonging the service time of the body side member. Furthermore, the edge of a carrier sheet will be covered by the rolled adhesive layer then constituting the surface contacting the stoma and thus, direct contact between the edge and the surface
10 of the stoma is avoided.

The second adhesive surface is preferably protected by a release liner until the application of the body side member.

- 15 It is preferred that the adhesive wafer is made from an adhesive comprising hydrocolloids for providing a capacity for absorbing humidity for prolonging the service time. The use of a hydrocolloid-containing adhesive will also provide for an automatic sealing against the surface of the stoma after rolling the edge of the hole of the ostomy appliance due to the expansion of the adhesive upon
20 absorption of humidity.

In a preferred embodiment the second surface of a part of the carrier sheet surrounding the stoma is provided with a hydrophobic adhesive.

- 25 A hydrophobic adhesive not comprising water-absorbing constituents is more stable against the action of aggressive exudates, which will delay the deterioration of the adhesive wafer, especially when the entire surface within the boundaries of the coupling is covered. In a preferred embodiment of the invention the hydrophobic adhesive loses its adhesiveness when wetted with exudates
30 from the stoma. Thus, incidental movements of the stoma will not expand the hole of the body side member permanently and the risk of adhesion of the wall of a collecting bag to the distal surface is avoided.

In another preferred embodiment the carrier sheet is absent in on a part of the second surface of the wafer the adhesive wafer surrounding the stoma. This embodiment provides in itself for a thinner area next to the central hole facilitating the rolling of the edge and also eliminates the stiffness provided by the carrier sheet in this area.

5 In this embodiment, the adhesive surface on the second surface of the adhesive wafer may be constituted of the second surface itself, especially if the exposed second surface is an adhesive showing slow absorption of humidity, or a second 10 layer of adhesive may be disposed in this area. When using a hydrophobic adhesive it is preferred that this adhesive stretches under the edge of the carrier sheet for providing a better sealing and protection of a hydrocolloid adhesive.

15 In a further embodiment of the invention, the thickness of the adhesive wafer of the body side member is smaller in the area next to the central hole for accommodating the stoma for further facilitating the rolling thereof

20 In a preferred embodiment of the invention the first adhesive surface of the body side member is covered with a release liner having an indication of the size of the hole of an ostomy appliance of the invention for accommodating an ostomy, at the surface in contact with the adhesive (distal as compared to the ostomy) for facilitating a customisation of the hole. In the alternative, the indication may be placed on the side facing away from the body side member (proximal as compared to the ostomy) if the release liner is transparent. In an especially 25 preferred embodiment of the invention a customised cutting guide as the one disclosed in WO 00/25709 is used.

30 In a preferred embodiment of the invention the part of the adhesive wafer surrounding the stoma is in the form of an exchangeable sealing member disposed in the hole of the wafer and having a hole for accommodating a stoma. This allows for a larger period of time between exchanges of the body side member itself reducing the stress posed on the skin.

A body side member of the invention is preferably provided with coupling means for releasable attachment of a receiving bag.

- The coupling means may be any system known per se for attaching receiving bags to ostomy body side members and may suitably be matching coupling rings of the type disclosed in WO 93/18725 or WO 94/18919 or matching flanges for adhesive connection of the type disclosed in U.S. Patent No. 5,800,415.
- 5

- It is preferred that the coupling means are matching coupling rings.
- 10 The coupling ring may e.g. be attached to the carrier sheet by adhesive means or preferably by welding

- In another aspect the invention relates to an ostomy sealing member in the form
15 of a mouldable mass or ring having a first surface which shows a sufficient adhesiveness to adhere to the skin and to seal around a stoma and between the stoma and an ostomy appliance adapted to receive secretions from the stoma, which sealing member has a second surface facing away from the user optionally being covered by a top film, which sealing member shows a sufficient cohesion to
20 be removed in one piece, independently of removal of the ostomy appliance body side member without leaving residues of adhesive on the skin or the ostomy appliance, said sealing member having a hole for accommodating a stoma and said sealing member having balanced plastic and elastic properties allowing an enlarging of the hole for receiving a stoma by rolling up the inner rim of the hole
25 before placing the sealing member around the stoma and wherein a part of the second surface surrounding the hole shows adhesive properties compatible with first adhesive surface.

- The adhesive surfaces of a sealing member of the invention are suitably covered
30 by release liners to be removed before application as discussed above.

In a third aspect the invention relates to a method of applying an ostomy appliance body side member comprising an adhesive wafer having a first adhesive surface for securing the appliance to a user's skin, said wafer having a second surface being covered with a carrier sheet and a hole for receiving a stoma wherein the hole is enlarged by rolling an inner rim of the second hole adapting of the hole to the size of the stoma, locking the rolled rim in its rolled position by contacting an adhesive surface at a part of the wafer surrounding the stoma, aligning the stoma and the hole of the ostomy appliance body side member for accommodating the stoma and placing the body side member on the abdomen of the ostomate with the stoma projecting into the hole.

In a fourth aspect the invention relates to a method of applying an ostomy appliance body side member comprising an adhesive wafer having a first adhesive surface for securing the appliance to a user's skin, said wafer having a second surface being covered with a carrier sheet and a first hole comprising a sealing member having a second hole for receiving a stoma wherein the second hole of the sealing member is enlarged by rolling an inner rim of the second hole of the sealing member which sealing member has a second surface facing away from the user optionally being covered by a top film, which sealing member shows a sufficient cohesion to be removed in one piece, independently of removal of the ostomy appliance body side member without leaving residues of adhesive on the skin or the ostomy appliance, and said sealing member having balanced plastic and elastic properties allowing an enlarging of the second hole for receiving a stoma by rolling up the inner rim of the hole before placing the sealing member around the stoma and wherein a part of the second surface surrounding the hole shows adhesive properties compatible with first adhesive surface, adapting the hole to the size of the stoma, locking the rolled rim in its rolled position by contacting an adhesive surface at a part of the wafer surrounding the stoma, aligning the stoma and the second hole of the ostomy sealing member and placing the same in the first hole of the body side member on the abdomen of the ostomate with the stoma projecting into the second hole.

An ostomy body side member according to the invention may be produced from standard materials normally used for preparation of disposable ostomy and wound and incontinence devices. Thus, the carrier sheet may be any suitable thermoplastic material known per se for use in the preparation of ostomy

- 5 appliances e.g. a foam, a non-woven layer or a polyurethane, polyethylene, polyester or polyamide film and the adhesive wafer itself may be made from a medical grade barrier adhesives comprising hydrocolloids known in the art such as the formulations being disclosed, for example in US Patents Nos. 4,367,732, 5,051,259 or 5,714,225.

10

A receiving bag for use with the body side member of the invention may be known per se and comprise front and rear walls sealed together along the rim and provided with an inlet opening may be made in analogy with and from materials conventionally used for the preparation of ostomy appliances.

15

Such materials are suitably films composed of any suitable material, which is heat sealable and sufficiently impervious for unpleasant odours such as polyolefin films or combinations of such films, e.g. polyethylene or a coextrudate of polyethylene and polyvinylidene chloride.

20

A protective cover or release liner may for instance be siliconized paper. It does not need to have the same contour as the dressing, e.g. a number of dressings may be attached to a larger sheet of protective cover. The protective cover is not present during the use of the dressing of the invention and is therefore not an essential part of the invention.

25

Description of the Preferred Embodiments

The invention is now explained more in detail with reference to the drawings showing preferred embodiments of the invention.

30

Reference is made to Fig. 1 which shows a cross sectionally view of an ostomy body side member 1 of the state of the art comprising an adhesive wafer 2 having

a first surface for securing the appliance to the user's skin S, said wafer having a second surface being covered by a carrier sheet 3 conventionally used, e.g. a LDPE or a PU film, which wafer has a hole for receiving a stoma wherein the part of the adhesive wafer surrounding the stoma shows balanced plastic and elastic properties allowing an adaptation of the size of the hole of the ostomy appliance to a stoma by enlarging the hole by rolling up the inner rim thereof for accommodating the stoma. Furthermore, the body side member is provided with a coupling ring 4 for attachment of a receiving bag provided with a matching coupling ring and a release liner 5 for protecting the first adhesive surface until use.

Fig. 2 shows a cross sectional view of an embodiment of an ostomy appliance body side member 10 according to the invention comprising an adhesive wafer 12 having a first adhesive surface for securing the appliance to the user's skin S, said adhesive having a second surface being covered by a carrier sheet 13 conventionally used for ostomy appliances. Furthermore, the body side member is provided with a coupling ring 14 for attachment of a receiving bag and a release liner 15 for protecting the first adhesive surface until use. The carrier sheet is absent on a central part of the second surface of the adhesive wafer 12 surrounding the stoma. The body side member comprises a second layer of adhesive 16 disposed on the second surface of the wafer surrounding the stoma and stretching under the inner rim of the carrier sheet 13 and a release liner 17 covering said second layer of adhesive. The release liner is to be removed before application of the appliance. A receiving bag provided with a matching coupling ring may be secured to the coupling ring in a manner known per se.

Fig. 3 shows a cross sectional view of a sealing member of the invention comprising an adhesive wafer 22, having a carrier sheet 23 having mechanical properties similar to the adhesive which wafer is thinner in the area next to the central hole for accommodating the stoma and is provided with a release liner 25 for protecting the adhesive surface until use. The sealing member comprises a second layer of adhesive 26 disposed on the second distal surface of the

member surrounding the stoma. The sealing member is furthermore provided with a flange part 28 for attaching the sealing member to the surface of a body side.

- In Fig. 4, the rim of the central hole has been rolled up forming a torus 29 and
- 5 revealing a larger part of the surface of the release liner 25 below and of the indication of the size of the hole.

Fig. 5 shows a top view from the distal side of a separate sealing member 20 of the invention having a hole for accommodating a stoma in which the rim of the

10 hole has been partially rolled for forming the torus into a shape 30 to fit an irregular stoma and showing the indication of the size of the hole placed on a release liner 25 visible through the hole.

Claims

1. An ostomy appliance body side member comprising an adhesive wafer having a first surface for securing the appliance to the user's skin, said wafer having a second surface being covered with a carrier sheet which wafer has a hole for receiving a stoma wherein the part of the adhesive wafer surrounding the stoma shows balanced plastic and elastic properties allowing an adaptation of the size of the hole of the ostomy appliance to a stoma by enlarging the hole by rolling up the inner rim thereof for accommodating the stoma and wherein the second surface of a part of the wafer surrounding the stoma shows adhesive properties compatible with the adhesive wafer.
5
2. A body side member as claimed in claim 1 wherein the second surface of a part of the carrier sheet surrounding the stoma is provided with a hydrophobic adhesive.
10
3. A body side member as claimed in claim 1 wherein the carrier sheet is absent on a part of the second surface of the wafer the adhesive wafer surrounding the stoma.
15
4. A body side member as claimed in any of claims 1-3 wherein the part of the adhesive wafer surrounding the stoma is in the form of an exchangeable sealing member disposed in the hole of the wafer and having a hole for accommodating a stoma.
20
5. A body side member as claimed in any of claims 1-4 being provided with coupling means for releasable attachment of a receiving bag.
25
6. A body side member as claimed in claim 5 wherein the coupling means are matching coupling rings.
30

7. An ostomy sealing member in the form of a mouldable mass or ring having a first surface which shows a sufficient adhesiveness to adhere to the skin and to seal around a stoma and between the stoma and an ostomy appliance adapted to receive secretions from the stoma, which sealing member has a second surface facing away from the user optionally being covered by a top film, which sealing member shows a sufficient cohesion to be removed in one piece, independently of removal of the ostomy appliance body side member without leaving residues of adhesive on the skin or the ostomy appliance, said sealing member having a hole for accommodating a stoma and said sealing member having balanced plastic and elastic properties allowing an enlarging of the hole for receiving a stoma by rolling up the inner rim of the hole before placing the sealing member around the stoma and wherein a part of the second surface surrounding the hole shows adhesive properties compatible with first adhesive surface.
- 5 10 15 20 25 30
8. A method of applying an ostomy appliance body side member comprising an adhesive wafer having a first adhesive surface for securing the appliance to a user's skin, said wafer having a second surface being covered with a carrier sheet and a hole for receiving a stoma wherein the hole is enlarged by rolling an inner rim of the second hole adapting of the hole to the size of the stoma, locking the rolled rim in its rolled position by contacting an adhesive surface at a part of the wafer surrounding the stoma, aligning the stoma and the hole of the ostomy appliance body side member for accommodating the stoma and placing the body side member on the abdomen of the ostomate with the stoma projecting into the hole.
9. A method of applying an ostomy appliance body side member comprising an adhesive wafer having a first adhesive surface for securing the appliance to a user's skin, said wafer having a second surface being covered with a carrier sheet and a first hole comprising a sealing member having a second hole for receiving a stoma wherein the second hole of the sealing member is enlarged by rolling an inner rim of the second hole of the sealing member which sealing

- member has a second surface facing away from the user optionally being covered by a top film, which sealing member shows a sufficient cohesion to be removed in one piece, independently of removal of the ostomy appliance body side member without leaving residues of adhesive on the skin or the ostomy
- 5 appliance, and said sealing member having balanced plastic and elastic properties allowing an enlarging of the second hole for receiving a stoma by rolling up the inner rim of the hole before placing the sealing member around the stoma and wherein a part of the second surface surrounding the hole shows adhesive properties compatible with first adhesive surface, adapting the hole to
- 10 the size of the stoma, locking the rolled rim in its rolled position by contacting an adhesive surface at a part of the wafer surrounding the stoma, aligning the stoma and the second hole of the ostomy sealing member and placing the same in the first hole of the body side member on the abdomen of the ostomate with the stoma projecting into the second hole.

15

20

Abstract**An Ostomy Appliance**

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An ostomy appliance body side member comprising an adhesive wafer having a first adhesive surface for securing the appliance to the user's skin, said wafer having a second surface being covered with a carrier sheet which wafer has a hole for receiving a stoma wherein the part of the adhesive wafer surrounding the

10 stoma shows balanced plastic and elastic properties allowing an adaptation of the size of the hole of the ostomy appliance to a stoma by enlarging the hole by rolling up the inner rim thereof for accommodating the stoma and wherein the second surface of a part of the wafer surrounding the stoma shows adhesive properties compatible with the adhesive wafer enables a simple, safe and reliable
15 customisation of the hole of a body side member without the use of tools and at the same time provides means for reducing the risk of causing injury to or constriction of the stoma.

Patent- og
Varemærkestyrelsen

10 JAN 2003

Modtaget

1



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Fig. 1

Fig. 2

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Fig. 3

Patent- og
Varemærkestyrelsen

10 JAN. 2003

Modtaget

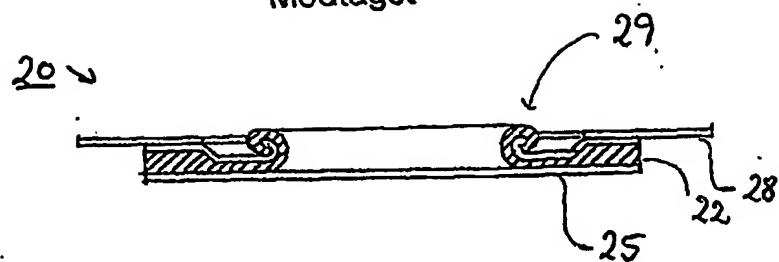


Fig. 4

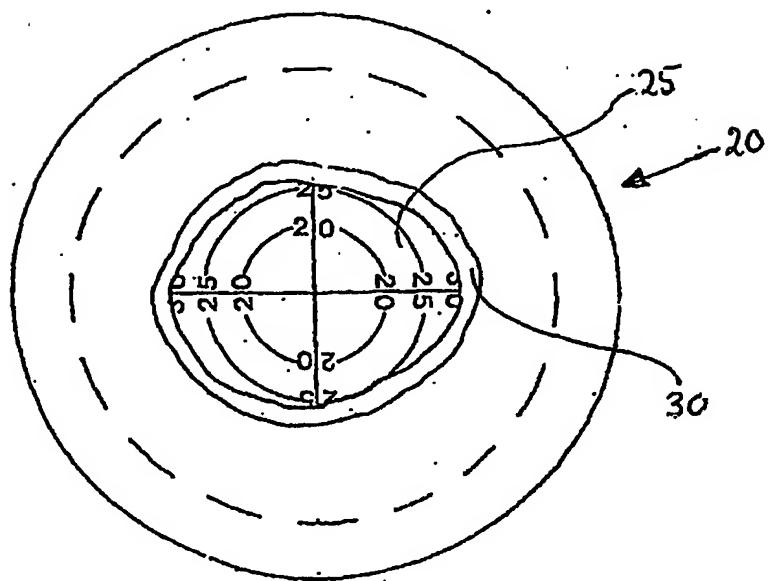


Fig. 5

INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/DK2004/000011

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F5/443 A61F5/448

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/004477 A1 (GOTHJAELESEN LAILA BUSK ET AL) 2 January 2003 (2003-01-02) paragraph '0053!; figures paragraph '0084! ---	1-3,6-11
X	WO 98/53771 A (GOTHJAELESEN LAILA BUSK ;CIOK DANUTA (DK); COLOPLAST AS (DK); SLET) 3 December 1998 (1998-12-03) cited in the application page 8, line 8 -page 9, line 5; figures ---	1-3,6-8, 10,11
A	US 4 095 599 A (SIMONET-HAIBE DENISE) 20 June 1978 (1978-06-20) column 4, line 38 -column 5, line 28; figures ---	1,4,6,8, 11 -/-

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the International filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the International filing date but later than the priority date claimed

- "T" later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "&" document member of the same patent family

Date of the actual completion of the International search

24 May 2004

Date of mailing of the International search report

08/06/2004

Name and mailing address of the ISA

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/DK2004/000011

C(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	GB 2 351 238 A (SQUIBB BRISTOL MYERS CO) 27 December 2000 (2000-12-27) page 8, line 12 -page 9, line 13; figures 1,4 -----	1,2,6,8, 9,11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK2004/000011

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 12-14 because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte	nal Application No
	PCT/DK2004/000011

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2003004477	A1 02-01-2003	DK 116696 A AU 721675 B2 AU 4616397 A CA 2269575 A1 CN 1233945 A WO 9817212 A1 EP 0998247 A1 JP 2001502570 T NO 991905 A AT 232747 T AU 729075 B2 AU 4616297 A CA 2269325 A1 CN 1233965 A DE 69719206 D1 DE 69719206 T2 WO 9817329 A1 EP 0938349 A1 ES 2189981 T3 JP 2001502569 T NO 991904 A US 2002120032 A1 AT 219913 T AU 726169 B2 AU 7425898 A BR 9809692 A CA 2291035 A1 CN 1258208 T DE 69806379 D1 DE 69806379 T2 DK 68998 A WO 9853771 A1 DK 984750 T3 EP 0984750 A1 ES 2177009 T3 JP 2001526576 T NO 995740 A PL 336960 A1 US 6332879 B1 AU 7426598 A WO 9854269 A1 EP 0985006 A1	23-04-1998 13-07-2000 15-05-1998 30-04-1998 03-11-1999 30-04-1998 10-05-2000 27-02-2001 22-06-1999 15-03-2003 25-01-2001 15-05-1998 30-04-1998 03-11-1999 27-03-2003 13-11-2003 30-04-1998 01-09-1999 16-07-2003 27-02-2001 22-06-1999 29-08-2002 15-07-2002 02-11-2000 30-12-1998 11-07-2000 03-12-1998 28-06-2000 08-08-2002 06-03-2003 27-11-1998 03-12-1998 28-10-2002 15-03-2000 01-12-2002 18-12-2001 18-01-2000 31-07-2000 25-12-2001 30-12-1998 03-12-1998 15-03-2000
WO 9853771	A 03-12-1998	AT 219913 T AU 721675 B2 AU 4616397 A AU 726169 B2 AU 7425898 A BR 9809692 A CA 2269575 A1 CA 2291035 A1 CN 1233945 A CN 1258208 T DE 69806379 D1 DE 69806379 T2 DK 68998 A WO 9817212 A1 WO 9853771 A1	15-07-2002 13-07-2000 15-05-1998 02-11-2000 30-12-1998 11-07-2000 30-04-1998 03-12-1998 03-11-1999 28-06-2000 08-08-2002 06-03-2003 27-11-1998 30-04-1998 03-12-1998

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int'l	Application No
	PCT/DK2004/000011

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9853771	A	DK 984750 T3 EP 0998247 A1 EP 0984750 A1 ES 2177009 T3 JP 2001526576 T JP 2001502570 T NO 991905 A NO 995740 A PL 336960 A1 US 2003004477 A1 US 6332879 B1	28-10-2002 10-05-2000 15-03-2000 01-12-2002 18-12-2001 27-02-2001 22-06-1999 18-01-2000 31-07-2000 02-01-2003 25-12-2001
US 4095599	A 20-06-1978	FR 2342716 A1 BE 850153 A1 BR 7700649 A CA 1098002 A1 CH 610519 A5 DE 2703032 A1 DK 68077 A ES 225569 Y GB 1521796 A IT 1083451 B JP 1123148 C JP 52100796 A JP 57015893 B LU 76528 A1 MX 143096 A NL 7701220 A , B, SE 424261 B SE 7701721 A YU 43377 A1	30-09-1977 06-07-1977 04-10-1977 24-03-1981 30-04-1979 25-08-1977 19-08-1977 01-07-1977 16-08-1978 21-05-1985 12-11-1982 24-08-1977 01-04-1982 18-09-1978 13-03-1981 22-08-1977 12-07-1982 19-08-1977 31-05-1982
GB 2351238	A 27-12-2000	GB 2340398 A AU 759200 B2 AU 4351499 A CA 2280107 A1 EP 0985390 A1 GB 2351237 A , B JP 2000051258 A NZ 337055 A NZ 509775 A US 6709421 B1 ZA 9905162 A	23-02-2000 10-04-2003 09-03-2000 13-02-2000 15-03-2000 27-12-2000 22-02-2000 30-03-2001 30-03-2001 23-03-2004 12-02-2001

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